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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,847	10/26/2001	Charles E. Hart	00-100	9351

7590 04/08/2003

ZymoGenetics, Inc.  
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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/039,847	HART ET AL.
Examiner	Art Unit	
Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

**THE MAILING DATE OF THIS COMMUNICATION**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 03 February 2002 .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 13-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 13-20 is/are rejected.

7)  Claim(s) 20 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 26 October 2001 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.      6)  Other: \_\_\_\_\_ .

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group III and species election of x=250 and y=370 with traverse in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the different species share a common utility and a substantial structural feature essential to that utility. Applicant's arguments are found persuasive and the requirement for an election of species is withdrawn.

Applicant has not traversed the restriction requirement. The requirement is still deemed proper and is therefore made FINAL. Claims 13-20 are pending and under examination in this application.

### *Specification*

2. The use of the trademarks FLAG™, ATCCTM, AMERICAN TYPE CUTURE COLLECTION™, BAC-TO-BAC™, NUCTRAP™, EXPRESSHYB™, PEFABLOC™, SEPHAROSE™, POROS™, NUPAGE™, FASTSILVER™, XCELL II™, SUPERSIGNAL™, LUMIIMAGER™, SEAPLAQUE GTG™, QIAQUICK™, QIAGEN™, ELECTROMAX DH10B™, FASTLINK™, SEPHADEX™, GC-MELT™, PHARMACIA™, REDIPRIME™, AMERSHAM™, CLONTECH™, MILLIPORE™, SEPHACRYL™, NOVEX™, BIOMAX™, and LIFE TECHNOLOGIES™ have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Objections*

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3. Applicant is advised that should claim 13 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patent 6,495,668 (Gilbert et al., 2002) and U.S. patent 6,468,543 (Gilbertson et al., 2002).

Each of the applied references has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the references, they constitute prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

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either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the references was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The '668 patent teaches instant SEQ ID NO: 2 as zvegf4 and teaches polypeptides consisting of residues 19-370, 35-370, 52-370, 246-370, 250-370, 258-370, and 180-370 as containing the growth factor domain (table 1, column 10). Administration of zvegf4 proteins to non-human animals is taught in, in for example, columns 29-42, and to human and veterinary subjects in column 38, lines 59-67, and column 39, lines 1-22, for example. Administration of the protein via infection of animals with a zvegf4-encoding adenovirus vector is taught in column 58, lines 21-67, and column 59, lines 1-8. That proliferation of cells in the kidney was observed is explicitly set forth in lines 64-67 of column 58 and lines 1-8 of column 59. However, it is not necessary that the effects on kidney tubule epithelial cells or precursor cells claimed by Applicant have been observed in the example of the '668 patent; such effects would inherently occur on administration of zvegf4, regardless of whether they were recognized at the time. Thus, the '688 patent discloses each of the limitations of instant claims 13-20 and therefore anticipates Applicant's invention.

The '543 patent teaches instant SEQ ID NO: 2 as zvegf4 and teaches polypeptides consisting of residues 19-370, 35-370, 52-370, 246-370, 250-370, 258-370, and 180-370 as containing the growth factor domain (table 1, column 4). Administration of zvegf4 proteins is taught in column 9, lines 59-67 and column 10, lines 1-64. That the proteins may be administered systemically is taught in column 10, lines 19-24. Thus, although patent is directed to methods of promotion of bone growth, the '543 patent teaches administration of zvegf4

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proteins in a way that would inherently affect kidney cells and is not limited to formulations that would only have local effects. Administration of zvegf4 via infection of animals with a zvegf4-encoding adenovirus vector is taught in column 21, lines 20-66, and column 22, lines 1-5. That proliferation of cells in the kidney was observed is explicitly set forth in lines 64-67 of column 21 and lines 1-5 of column 22. However, as stated above, it is not necessary that Applicant's claimed effect have been recognized; such effects would have inherently occurred on exposure to zvegf4. Thus the '543 patent discloses each of the limitations of instant claims 13-20 and therefore anticipates Applicant's invention.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 13-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 9, and 10 of U.S. Patent No. 6468543. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims 13-20 are drawn to methods of administering zvegf4 proteins to affect kidney tubule epithelial cells or precursor cells. As stated above, systemic administration of

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zvegf4 would inherently result in these effects, regardless of whether they were observed at the time. Thus claims 1, 5, 9, and 10 of the '543 patent are not patentably distinct from methods of using zvegf4 proteins to affect bone growth; neither the stated intention of affecting bone growth in the '543 patent nor the intention of affecting kidney cells in the instant claims changes the method itself, or the results that would be obtained. The region of zvegf4 claimed in the instant claims are either explicitly claimed in claims 1, 5, 9, or 10, or are variants taught as containing the growth factor region in table 1, column 4, of the '543 patent. Note that MPEP§804 states, The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557.

The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Janet Andres, Ph.D.  
Patent Examiner

April 7, 2003